REMARKS

This paper is provided in response to the Office Action mailed December 5, 2008. By way of response, Applicant has amended claim 1. No new matter has been added. Claims 1 and 3-10 are pending.

Applicant submits the amended claims are supported by the specification as filed. Claim 1 now includes the structure of vitamin K1 oxide instead of the structure formerly presented in dependent claim 2. The structure of vitamin K1 oxide is known and the compound is referred to by name throughout the specification as filed. Thus, the amendment of claim 1 is proper.

For the reasons presented below, Applicant respectfully submits that the amended claims are in condition for allowance, and notification to that effect is earnestly solicited.

Examiner Interview

Applicant's undersigned representative thanks the Examiner for courtesies extended during the telephonic interview on June 5, 2009. The Examiner suggested that unexpected results would be useful in overcoming the obviousness rejection. An unexpected result is discussed below.

Rejection of Claims Under 35 U.S.C. § 103(a)

The Examiner maintained the rejection of claims 1 and 3-10 under 35 U.S.C. 103(a) as being obvious over Elson, US 5,510,391, in view of Ryall et al., J. Med. Chem. 1990 (33), 1790-1797. Although the rejection was not applied to the compound recited in amended claim 1, it is addressed insofar as it might apply. Applicants respectfully traverse the rejection.

Applicant respectfully submits that the combined prior art references do not disclose or suggest the presently claimed invention. The Elson reference discloses a method that can employ a vitamin K analog. This reference admits that the vitamin K analog is limited to "vitamins K-3, K-4, K-5, K-6, and K-7" (column 1, lines 37-39). The Elson reference does not even mention oxides or epoxides. The Ryall et al. reference discloses the existence of vitamin K1 epoxide and that certain specified derivatives of this compound inhibit the enzyme vitamin K1 epoxide reductase. However, vitamin K1 epoxide itself does not inhibit this enzyme.

The Office Action asserts that inhibitors of vitamin K1 epoxide reductase would be expected to be active in the method of the Elson reference. The presently claimed method employs vitamin K1 epoxide, which does not inhibit this enzyme. Therefore, the logic of the Office Action fails, and the combined references neither teach nor suggest the presently claimed invention.

Unexpected Results

The Office Action suggests that unexpected results for the claimed compound compared to the prior art can overcome the obviousness rejection. First, since the compound employed in the presently claimed method does not have the pharmacological activity of the compounds of the Ryall et al. reference, on its face the beneficial activity of the claimed compound is surprising.

Second, Applicants resubmit herewith as Exhibit A a Declaration originally submitted earlier in prosecution of this application. This Declaration compares the presently claimed method employing vitamin K1 oxide with the method of the Elson reference, which employs vitamin K1. Unexpectedly, vitamin K1 oxide was surprisingly more effective than vitamin K1 in reducing the observed level of bruising. Accordingly, the presently claimed method exhibits an unexpected result compared to the cited prior art reference. Thus, this rejection should be withdrawn.

Detailed Rebuttal of Rejection

There are additional reasons why the person skilled in the art would not use analogs beyond those listed in the Elson patent ("vitamins K-3, K-4, K-5, K-6, and K-7" (column 1, lines 37-39)). That is because each of these analogs has the common methylated naphthalene ring which is aromatic and known to have some particular chemical behavior. In contrast, vitamin K1 oxide does not include this aromatic system, the presence of the epoxide breaks the aromatic. There is no teaching mentioned or suggested in Elson publication that will lead the person skilled in the art to break this aromatic ring which is known to have an importance for the properties of the vitamin K analogs discussed in the Elson patent (vitamins K1, K2, K3, K4, K5, K6 and K7).

The Ryall et al. reference describes substituted vitamin K epoxide analogs which could be used as new competitive inhibitors of vitamin K1 epoxide reductase. Vitamin K epoxide reductase is an enzyme that reduces vitamin K after it has been oxidized in the carboxylation of glutamic acid. One of its sub-units is the target of the known anticoagulant warfarin and other coumarin drugs block the action of vitamin K epoxide reductase.

The Ryall et al. reference proposes that the vitamin K1 analogs might serve as new class of potential (but not proved) anticoagulant agents that act as competitive inactivators of vitamin K1 epoxide reductase like warfarin (see Ryall et al. reference, page 1791, left column, lines 1 to 4). This reference mentions that "since warfarin is a noncompetitive inhibitor of the enzyme, it will be interesting to determine the effect of competitive inhibition on coagulation. In particular, the effect of these compounds on warfarin-resistant rats should be a valuable endeavour" (see Ryall et al. reference, page 1795, right column, lines 12 to 16). The Ryall et al. reference suggests, but does not prove that Vitamin K1 epoxide could be potential anticoagulant like warfarin (which means that it could have potential effect in the prevention of thrombosis and embolism disorders).

However, this reference does not disclose or suggest that vitamin K1 epoxide could be used for the treatment of dermatological lesions of a mammal.

Contrary to the assertions in the Office Action, one of ordinary skill in the art would not be motivated to use the enzyme inhibitors disclosed by the Ryall et al. reference for the formulation disclosed by the Elson patent with the expectation that the compound would treat efficiently dermatological lesions. Furthermore, there is no teaching or suggestion in the state of the art that this mechanism of dermatological conditions treatment is obtained by the inhibition of vitamin K1 epoxide reductase enzyme.

Contrary to the assertions in the Office Action, such mechanism could be proposed in the treatment of diseases by warfarin such as thrombosis or embolism, but there is no suggestion that these compounds could have effect upon dermatological lesions.

The Office Action refers to a statement made in the Background section of the present patent application, with particular reference to GB-744376. The portion of the Background section discussed in the Office Action refers to conventional formulations for intravenous injections, while the compositions of the present invention are presented for topically application

of a cosmetic composition having preferably the form of a cream, a gel, a lotion or a liquid (see claims 7 and 9).

Conclusion

Accordingly, based on the foregoing differences, Applicant respectfully submits that the presently claimed methods are neither taught nor suggested by the references cited in this rejection, and withdrawal of this rejection is earnestly solicited.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

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PATENT TRADEMARK OFFICE

Respectfully submitted,

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